REMARKS

A check for the fee for one month extension of time accompanies this response. Any additional fees that may be due in connection with the filing of this paper, if the attached check is in the wrong amount, improper or is missing, or with this application during its entire pendency, may be charged to Deposit Account No. 50-1213. If a Petition for an Extension of Time is required, this paper is to be considered such petition.

Claims 1-41 are pending in this application. Claims 40 and 41 are added herein. Claims 1-4, 6-24 and 26-39 are amended herein. Claims 1-4, 6-24, 26-31 are amended to correct typographical and formatting errors. Claims 1, 32 and 39 are amended to more clearly point of the subject matter of the claim. Amendments find basis in the specification as originally filed. In particular, basis for new claim 40 can be found in the specification on page 11, lines 9-11 and page 12, lines 13-16. The abstract of the disclosure is amended to delete the legal phraseology and correct a typographical error. No new matter is added.

REJECTION OF CLAIMS 13, 35 AND 38 UNDER 35 U.S.C. §112 SECOND PARAGRAPH

Claims 13, 35 and 38 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant Claim 13

It is alleged in the Office Action that claim 13 is vague and indefinite for the recitation "the oxidant diffuses into the oxidant releasing member". The Office Action suggests that the diffusion should be into the lumen of the medical device. Applicant disagrees.

Instant claim 13 recites:

> The method of claim 12 wherein the oxidant releasing member has an elongated body configured to be slidably inserted into the lumen of the medical device, and further including, before step (b), exposing the oxidant releasing

member to a formulation which generates the oxidant so that the oxidant diffuses into the oxidant releasing member.

Claim 12 depends from claim 2, which in turn depends from claim 1. The oxidant releasing member in claim 12 is exposed to a formulation that generates the oxidant. The oxidant generated in the formulation diffuses into the oxidant releasing member which is then inserted into the medical device. The oxidant releasing member thus provides a source of oxidant to the medical device. Applicant respectfully requests reconsideration and removal of the objection.

Claims 35 and 38

The Office Action alleges that the recitation of "the patient" in claims 35 and 38 lack proper antecedent basis.

Claims 35 and 38 have been amended herein to recite "a patient". Applicant respectfully requests reconsideration and removal of the objection.

REJECTION OF CLAIMS 1-4, 8-11, 16-23 and 32-39 UNDER 35 U.S.C. §102(b)

Claims 1-4, 8-11, 16-23 and 32-39 are rejected under 35 U.S.C. § 102(b) as anticipated by Davis (U.S. Patent No. 5,562,652). It is alleged in the Office Action that Davis discloses the delivery of an iodine releasing solution into the body of an indwelling lumened medical device such that anti-infective activity is delivered thereto and through to the body of the patient being treated to lessen and eliminate infections of the site. The Office Action notes that the solution is water and body fluid activated. Applicant respectfully traverses the rejection.

RELEVANT LAW

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Spada, 15 USPQ2d 1655 (Fed. Cir, 1990), In re Bond, 15 USPQ 1566 (Fed. Cir. 1990), Soundscriber Corp. v. U.S., 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir.), cert. denied, 110 S.Ct.

154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention". In re Lang, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover it is incumbent on the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Instant claims

Independent claim 1 is directed to a method of providing anti-infective activity to a medical device, which includes the steps of providing a medical device that is at least in part within a patient; then delivering an oxidant generating formulation to the medical device, thereby exposing the medical device to an anti-infective oxidant, and transferring the anti-infective oxidant into a wall of the medical device.

Claims 2-4, 8-11 and 16-23 depend from claim 1 and further define the method of claim 1, the medical device and the anti-infective oxidant used therein as follows: claim 2 is directed to the method of claim 1 wherein the medical device has a lumen and the walls defining the lumen are exposed to the anti-infective oxidant; claim 3 further defines the medical device as a catheter having a shaft and a balloon; claim 4 depends from claim 2 and further includes the step of delivering a formulation that generates the oxidant into the lumen of the medical device. Claims 8, 9 and 11 depend from claim 4 and further describe the anti-infective oxidant in the method of claim 4. Claim 10 depends from claim 9 and describes generation of elemental iodine upon contacting with the body fluid in the method of claim 9. Claim 16 depends from claim 1 and further includes the step of diffusion of the oxidant to an outer surface of the medical device. Claims 17-19 depend from claim 1 and further define the anti-infective oxidant and transfer thereof to the medical device. Claim 21 further defines the formulation used in the method of claim 4. Claims 22 and 23 depend from claim 21 and further define the

binding agent and the anti-infective oxidant used in the method of claim 21. Thus, claims 1-4, 8-11, and 16-23 include as one element, exposing the medical device after it has been placed in the patient's body.

Claim 32 is an independent claim and is directed to a method of providing anti-infective activity to a medical device including the steps of exposing the medical device to a solution which produces an anti-infective oxidant by inserting an oxidant releasing member into the device and transferring a sufficient amount of anti-infective oxidant into a wall of the medical device to provide the medical device with anti-infective activity. Claims 33-38 depend from claim 32 and further define the anti-infective oxidant. Thus, claims 32-38 include as one element, exposing the medical device to a solution which produces an anti-infective oxidant by inserting an oxidant releasing member into the device.

Claim 39 is an independent claim directed to a method of providing anti-infective activity to a medical device including the steps of exposing an oxidant releasing member to a formulation which generates an anti-infective oxidant, so that the anti-infective oxidant diffuses into the oxidant releasing member; and inserting the anti-infective oxidant releasing member into the device so that the anti-infective oxidant diffuses from the oxidant releasing member into a wall of the medical device.

Claim 40 is an independent claim directed to a method of providing anti-infective activity to a medical device including the steps of inserting an oxidant releasing member into the device, wherein the member is configured to be adjacent to or in the device and transferring the anti-infective activity into a wall of the device. Claim 41 depends from claim 40 and further defines the method of claim 40.

Disclosure of Davis

Davis discloses a catheter with a closed reservoir that contains a water-activatable antiseptic agent. The device disclosed by Davis requires manufactured

reservoirs designed for holding water-activatable antiseptic agents. Davis further describes that the water-activatable antiseptic agent is present in the catheter reservoir **before** insertion of catheter in the body and is manufactured as such. Davis discloses that the amount, type and concentration of the water activatable antiseptic agent in reservoir is pre-determined and pre-contained **prior** to insertion in the body (see, column 5, lines 13-19). It is noted that since the antiseptic agent is water activatable, adding such agent to the device does not confer anti-infective activity on the device.

Differences from the instant claims

Claims 1-4, and 16

Claim 1 is directed to a method of providing anti-infective activity to a medical device and includes the steps of providing a medical device that is at least in part within a patient; then delivering the oxidant generating formulation to the medical device, thereby exposing the medical device to an anti-infective oxidant; and transferring the anti-infective oxidant into a wall of the device. Thus, in the instantly claimed method of claim 1 and dependent claims, the medical device is exposed to an oxidant generating formulation after it has been placed within a patient.

The catheter disclosed in Davis contains a closed reservoir that contains a water-activatable antiseptic agent before it is placed in patient's body. Therefore, the device disclosed in Davis is exposed to an anti-infective oxidant generating formulation before being placed in patient's body. Davis does not disclose a way to first place the device in the patient's body and then expose the device to a formulation that generates an anti-infective oxidant, as claimed in the method of claim 1 and dependent claims. Thus, Davis does not disclose a method that includes a step of introducing a device into a patient and then delivering a formulation that generates anti-infective oxidant in the medical device, thereby exposing the medical device to an anti-infective oxidant.

Since anticipation requires disclosure in a single reference of all the elements as claimed, Davis does not anticipate 1 nor does it anticipate any of the dependent claims 2-4, 8-11 and 16-23.

Claims 32-38

Claim 32 is an independent claim directed to a method of providing anti-infective activity to a medical device including the steps of exposing the medical device to a solution which produces an anti-infective oxidant by inserting an oxidant releasing member into the device and transferring a sufficient amount of anti-infective oxidant into a wall of the medical device to provide the medical device with anti-infective activity. Claims 33-38 depend from claim 32 and further define method of claim 32.

Davis does not anticipate claim 32 because it does not disclose a medical device that is rendered anti-infective by inserting an oxidant releasing member into the device as claimed in the method of claim 32. Since anticipation requires disclosure in a single reference of all the elements as claimed, Davis does not anticipate claim 32 nor does it anticipate any of the dependent claims 33-38.

Independent Claim 39

Claim 39 is an independent claim directed to a method of providing anti-infective activity to a medical device by exposing an oxidant releasing member to a formulation which generates an anti-infective oxidant, so that the anti-infective oxidant diffuses into the oxidant releasing member; and inserting the oxidant releasing member into the medical device so that the anti-infective oxidant diffuses from the oxidant releasing member into a wall of the medical device.

As discussed above, Davis does not disclose an oxidant releasing member that can be inserted in the medical device nor does it disclose exposing the medical device to the oxidant releasing member. Davis does not anticipate claim 39 because it does not disclose all the elements of claim 39.

Claims 40 and 41

Independent claim 40 is directed to a method of providing anti-infective activity to a medical device, including the steps of inserting an anti-infective oxidant releasing member into the device, wherein the member is configured to be adjacent to or in the device; and transferring the anti-infective oxidant into a wall of the medical device. Claim 41 further defines the method of claim 40.

Davis does not disclose an anti-infective oxidant releasing member configured to be adjacent to or in the device. Therefore it does not anticipate claim 40 and dependent claim 41.

REJECTION OF CLAIMS 5-7, 12-15 and 24-31 UNDER 35 U.S.C. §103(a)

Claims 5-7, 12-15 and 24-31 are rejected under 35 USC § 103(a) as being unpatentable over Davis as applied to claims 1-4, 8-11, 16-23 and 32-39 above, and further in view of Shikani *et al.* (U.S. Patent No. 5,762,638) and Shikani *et al.* (U.S. Patent No. 5,695,458). The Office Action notes that '638 teaches construction of a lumened, in-dwelling medical device of anti-infective releasing polymeric material formulated for the controlled, prolonged release of an anti-infective through the wall of the device into a patient. Further the Office Action notes that '458 teaches the provision of an anti-infective agent releasing structure within a blood obtainment configuration for release of the agent with blood contact for the purpose of affording anti-infective activity thereto. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to provide a structure mimicking the configuration of a lumened medical device and capable of releasing an anti-infective agent as taught in '458, but constructed of the polymeric material as in '683, for insertion of such a structure into a catheter in place of the reservoired delivery system set forth in Davis because it would allow for the provision of effective anti-infective delivery to pre-existing catheters not having the reservoir capacity. Applicant respectfully traverses the rejection.

RELEVANT LAW

In order to set forth a *prima facie* case of obviousness under 35 U.S.C. §103: (1) there must be some teaching, suggestion or incentive supporting the combination of cited references to produce the claimed invention (ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 329, 933 (Fed. Cir. 1984)) and (2) the combination of the cited references must actually teach or suggest the claimed invention. Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. Ex parte Gerlach, 212 USPQ 471 (Bd. APP. 1980). Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981), but it cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination (ACS Hosp. Systems, Inc. v Montefiore Hosp. 732 F.2d 1572, 1577. 221 USPQ 329, 933 (Fed. Cir. 1984)). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" W.L. Gore & Associates, Inc. v. Garlock Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

Under 35 U.S.C. §103, in order to set forth a case of *prima facie* obviousness the differences between the teachings in the cited reference must be evaluated in terms of the whole invention, and the prior art must provide a teaching or suggestion to the person of ordinary skill in the art to have made the changes that would produce the claimed product. *See, e.g., Lindemnann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 U.S.P.Q.2d 481, 488 (Fed. Cir. 1984). The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); *see, also, In re Papesh*, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963). MPEP 2143 states:

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference . . . must teach or suggest all the claim limitations.

In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Claims 5-7 and 12-15 and 24 (Claims dependent from claim 1)

Claims 5-7 depend from claim 4 and further define the steps in the method of claim 4. Claim 5 defines the step of inserting a tubular delivery member into the lumen of the medical device. Claims 6 defines the step of removing the oxidant generating formulation from the lumen of the medical device after transfer of an anti-infective oxidant into the walls of the device. Claim 7 further defines the step of inhibiting expulsion of the oxidant generating formulation from the lumen of the medical device by providing a viscosity increasing hydrogel in the oxidant generating formulation. Claim 12 depends from claim 2 and includes the step of inserting the oxidant releasing member into the lumen of the device. Claims 13-15 further define the oxidant releasing member and the anti-infective oxidant. Claim 24 depends from claim 4 and further includes the step of positioning an insert member into the lumen of the device to reduce the amount of formulation delivered.

Independent claim 25 and claims dependent thereon

Claim 25 is an independent claim directed to an oxidant releasing member having an elongated body configured to be slidably disposed within a lumen of a

medical device and an anti-infective oxidant releasably contained within the elongated body. Claims 26-31 further define the oxidant releasing member.

Differences between the instant claims and teachings of Davis (U.S. Patent No. 5,562,652)

As discussed above, Davis teaches a catheter with a closed reservoir which contains a water-activatable antiseptic agent. Davis further teaches that the water activatable antiseptic agent in the reservoir is pre-determined and **pre-contained prior** to insertion in the body. Davis does not teach or suggest that the medical device can be exposed to an oxidant generating formulation after being placed in the body. Nor does it teach or suggest that the device taught therein can be modified according to the instantly claimed methods where the device is exposed to an oxidant generating formulation after being placed in the body. Furthermore, as discussed below, none of the secondary references cure this defect.

Further, Davis does not teach or suggest an oxidant releasing member having an elongated body configured to be slidably disposed within a lumen of a medical device as claimed in claim 25. Davis teaches a medical device that contains a reservoir to hold an anti-infective agent. It does not teach or suggest an oxidant releasing member that can be inserted in the device. Furthermore, as discussed below, none of the secondary references cure this defect. Therefore Davis does not anticipate independent claim 25 and the claims dependent thereon.

Teachings of Shikani *et al.* (U.S. Patent No. 5,762,638)

U.S. Patent No. 5,762,638 teaches coating a medical device with a polymer that is loaded with anti-inflammatory agents and anti-microbial agents and programmed to release the drugs locally around the device at a relatively high concentration, in controlled and sustained fashion. The reference teaches that the drugs are released after the device comes in contact with body fluids or mucosa.

'638 patent does not teach or suggest that the medical device can be exposed to an oxidant generating formulation after the device has been placed in the body. Further, the reference does not teach or suggest an oxidant releasing member configured to be slidably disposed within a lumen of a medical device and an anti-infective oxidant releasably contained within the elongated body, as claimed claim 25 and further described in dependent claims 27-31. The reference teaches coating walls of a device with polymer loaded with anti-microbial agent.

Teachings of Shikani *et al.* (U.S. Patent No. 5,695,458)

U.S. Patent No. 5,762,638 teaches anti-infective coatings for non-implantable medical devices, such as hospital and laboratory equipment. '458 patent teaches iodine-loaded polymer coatings on containers or receptacles, such as blood bank equipment. The reference teaches coating inside and outside surfaces of blood and body fluid containers. The reference teaches polymer film strip or patch containing releasable iodine that can be adhered to the wall of a container.

'458 patent does not teach or suggest that the medical device can be exposed an oxidant generating formulation after it has been placed in the body. Further, '458 patent does not teach or suggest an oxidant releasing member configured to be slidably disposed within a lumen of a medical device and an anti-infective oxidant releasably contained within the elongated body, as claimed claim 25 and further described in dependent claims 27-31. The reference teaches coating inside and outside surfaces of blood and body fluid containers and polymer film strip or patch containing releasable iodine that can be adhered to the wall of a container.

Analysis

The Examiner has failed to set forth a prima facie case of obviousness

Claims 5-7, 12-15 and 24

None of the cited references, singly or in any combination thereof, teaches or suggests the method of claim 1 because they do not teach or suggest exposing a medical device to an oxidant generating formulation it has been placed in the patient's body. Therefore they can not teach or suggest any of the dependent claims 5-7, 12-15 and 24. Furthermore, several of the elements in the dependent claims are not taught or suggested by the cited references, singly or in any combination thereof. As discussed above, Davis does not teach or suggest delivering an oxidant generating formulation in the medical device after it has been placed in the patient's body and the secondary references by Shikani *et al.* do not supply the missing element of Davis.

Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness for the methods of claims 5-7, 12-15 and 24.

Claims 25-31

As discussed above, Davis does not teach or suggest an oxidant releasing member configured to be slidably disposed within a lumen of a medical device and an anti-infective oxidant releasably contained within the elongated body as claimed in claim 25. Therefore, it can not teach or suggest any of the dependent claims 26-31. Further, Shikani *et al.* do not supply the missing elements of Davis.

Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness for claims 25-31.

The combination of teachings of the cited references does not result in the instantly claimed oxidant releasing member

Furthermore, absent hindsight reconstruction, the combination of teachings of the references does not result in the presently claimed methods wherein the medical device is exposed to an oxidant generating formulation after it has been placed in the patient's body using an oxidant releasing member (claims 5-7, 12-15 and 24) and the oxidant releasing member itself, as claimed in claims 25-31. As noted above, Davis provides catheters having reservoirs to contain the anti-infective agent and Shikani *et al.*, in U.S.

Patent Nos. 5,695,458 and 5,762,638, provide anti-infective coatings for medical devices that can be implanted in body and non-implantable medical devices, respectively. Neither reference teaches or suggests that an oxidant generating formulation can be delivered in the lumen of a device after the device has been placed in the patient's body by inserting an anti-infective releasing member. There is no teaching in any of the references that would have suggested the use of a delivery member to deliver a formulation that generates anti-infective oxidant into the lumen of the device. Therefore, the combination of references would not have resulted in the medical device of the claimed methods.

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In view of the above, reconsideration and allowance of the application are respectfully requested.

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